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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,644	07/29/2002	John C Kappes	44276/242574 (5854-6)	1101

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,644

Applicant(s)

KAPPES ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9, 10, 12-16 and 60-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-10, 12-16 and 60-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This is a response to the amendment, paper No. 17, filed 10/04/04. Claim 1 has been amended. Claims 6-8, 11 and 17-59 have been canceled. New claims 61-70 have been added. Claims 1-5, 9-10, 12-16 and 60-70 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-5, 9-10, 12-16 and 60 are still rejected under 35 U.S.C. 112, second paragraph on the same ground as stated in the previous Office Action, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Applicants traverse the rejection and submit that 1) the structure of trans-viral vector comprising gag and pol is described in the specification and in the literature, therefore, the person skill in the art would understand the term of trans-activating vector; 2) the structure of viral particle is also disclosed in the specification on page 4 as a retrovirus that has undergone nucleic acid recombinant event; and 3) the metes and bounds of one or more help function is defined in the claim as a sequence consisting of retroviral cis-acting sequences and retroviral coding sequences. Wherein said genetic elements facilitate reverse transcription and integration. Applicant further asserted that with this functional limitation, the metes and bounds of cited genetic element should be clear.
4. Applicants' argument has been fully considered; however, it is not found persuasive because the limitation disclosed in the specification cannot read into claims. Furthermore, there is

many genetic elements that can be used for making the viral like particle or many polypeptide of a lentivirus can be used as a cis-acting element, the precise sequence structure cited in claims need to be clarified.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3, 4, 9, 10, 12-13, 15 and 61-70 are still rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (J. Virol. 1991, Vol. 65, No. 5, pp. 2220-2224) on the same ground as stated in the previous Office Action.

7. Applicants traverse the rejection and submit that the construct disclosed by Miller et al. comprises MoMLV gag-pol protein, whereas the claimed construct as explained on page 25, line 19 and in Example 8, as a trans-viral vector comprises a gag-pro but not a gag-pol packaging construct. Therefore, Miller et al. do not anticipate the claimed invention. Furthermore, Applicants argue that the help function provided in trans does not limit to env or pseudotype env thereof or tat or rev.

8. Applicants' argument has been fully considered; however, it is not found persuasive because the structural characteristic of claimed construct comprising Gag and pro without pol sequence is not cited in the rejected claims.

9. Claims 1, 3, 4, 9, 10, 12-13, 15 and 61-70 are still rejected under 35 U.S.C. 102(b) as being anticipated by Naldini et al. (Science 1996, Vol. 272, No. 5259, pp. 263-267) on the same ground as stated in the previous Office Action.

10. Applicants traverse the rejection and submit that the construct disclosed by Naldini et al. comprise gag and pol and it is not used for detecting the formation of functional gag or pol genes. Therefore, Naldini et al. do not anticipate the claimed invention.

11. Applicants' argument has been fully considered; however, it is not persuasive because as stated in the previous Office action, while the intended use of the method disclosed by Miller et

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al. is not for detecting the retroviral recombinant, the method told by Miller is for generating the retroviral recombinant, it simply comprising the same steps as the current claims. As the limitation of the claimed intended use does not change the manipulation of the claimed method, the claimed invention, is inherently anticipated by the cited reference.

Claim Rejections - 35 USC § 102/103

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 1-5, 9-10, 12-13, 15-16 and 60-70 are still rejected under 35 U.S.C. 102(a) as being anticipated by Kafri et al. (J. Virol. 1999, Vol. 73, No. 1, pp. 576-584) on the same ground as stated in the previous Office Action.

14. Claims 1-5, 9-10, 12-16 and 60-71 are still rejected under 35 U.S.C. 103(a) on the same ground as stated in the previous Office Action as being unpatentable over Kafri et al. (J. Virol. 1999, Vol. 73, No. 1, pp. 576-584) as applied to claims 1-5, 9-10, 12-13, 15-16 and 60 above, and further in view of Morgenstern et al. (Nucleic Acids Research 1990, Vol. 18, No. 12, pp. 3587-3596) for claim 14.

15. Applicants traverse the 102/103 rejection together, and submit that purpose of Kafri et al. is not used for detecting the function gag and pol gene. Therefore, it cannot be used for anticipated the claims since claims 1 and 61 cite the assay used for detecting functional gag and pol formation.

16. Applicants' argument has been fully considered; however, it is not found persuasive because while the intended use of the method disclosed by Kafri et al. is not for detecting the risk of forming RCR, it actually is a method for detecting the positive retroviral recombinant vector produced by the method, and it simply comprising the same steps as the current claims. As the limitation of the claimed intended use does not change the manipulation of the claimed method procedures, the rejections are maintained.

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17. Moreover, the reference by Morgenstern et al. do teach the missing part of Kafri et al. about using puromycin as the drug resistant gene selection. As there are no unexpected results have been provided, hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.


18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JAMES HOUSEL 12/26/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600